# **Complete Summary**

#### **GUIDELINE TITLE**

Endoscopy in patients with implanted electronic devices.

# **BIBLIOGRAPHIC SOURCE(S)**

Petersen BT, Hussain N, Marine JE, Trohman RG, Carpenter S, Chuttani R, Croffie J, Disario J, Chotiprasidhi P, Liu J, Somogyi L, Technology Assessment Committee. Endoscopy in patients with implanted electronic devices. Gastrointest Endosc 2007 Apr;65(4):561-8. [48 references] PubMed

## **GUIDELINE STATUS**

This is the current release of the guideline.

# **COMPLETE SUMMARY CONTENT**

**SCOPE** 

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INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY DISCLAIMER

## SCOPE

# **DISEASE/CONDITION(S)**

- Any disease or condition requiring endoscopy with electrocautery
- Patient injury and/or implanted electronic device damage or malfunction caused by electromagnetic interference during gastrointestinal endoscopy

#### **GUIDELINE CATEGORY**

Management Prevention Risk Assessment

#### **CLINICAL SPECIALTY**

Cardiology Gastroenterology Internal Medicine Surgery

#### **INTENDED USERS**

Physicians

# **GUIDELINE OBJECTIVE(S)**

To address the risks and the appropriate management strategies for endoscopy and the use of electrocautery in patients with implanted electronic devices including the following: (1) cardiac devices (pacemakers and defibrillators), (2) neurostimulators (deep brain, gastric, spinal cord, sacral nerve, and urinary bladder stimulators), and (3) drug-infusion pumps (chemotherapy and pharmacotherapy infusion pumps)

#### **TARGET POPULATION**

Patients with implanted electronic devices undergoing endoscopic electrocautery

**Note**: Risks of gastrointestinal endoscopy in patients with implanted electronic devices that are unrelated to electromagnetic interference are not addressed.

## INTERVENTIONS AND PRACTICES CONSIDERED

## **Cardiac Devices**

- 1. Determining the type of cardiac device, indication for the device, the patient's underlying cardiac rhythm, and degree of pacemaker-dependence before endoscopy
- 2. Consultation with the patient's cardiologist or heart rhythm specialist
- 3. Continuous electrocardiographic rhythm monitoring and pulse oximetry during the procedure
- 4. Considering the use of endoscopic devices with limited or no electromagnetic fields (EMF) and the lowest effective power output and the briefest application of the electrocautery device possible
- 5. Considering reprogramming the pacemaker to an asynchronous mode through application of a magnet over the pulse generator
- 6. Considering deactivation of the implantable cardioverter-defibrillator (ICS) by qualified personnel
- 7. Considering the use of bipolar cautery or a device with no EMF

# **Neurostimulatory Devices and Implanted Infusion Pumps**

- 1. Determining the type of electronic device, indication for the device and whether normal physiology is critically dependent upon the device
- Considering the use of endoscopic device with limited or no EMF and use of the lowest effective power output and the briefest application of the electrocautery device possible

3. Consultation with the primary device specialist before considering inactivation of the device output

## **MAJOR OUTCOMES CONSIDERED**

- Safety of endoscopic electrocautery use in patients with implanted electronic devices
- Adverse events related to electromagnetic interference during gastrointestinal endoscopy

## **METHODOLOGY**

# METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

# DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Evidence-based methodology is used, with a MEDLINE literature search to identify pertinent clinical studies on the topic and a MAUDE (Food and Drug Administration Center for Devices and Radiological Health) database search to identify the reported complications of a given technology. Both are supplemented by accessing the "related articles" feature of PubMed and by scrutinizing pertinent references cited by the identified studies. Controlled clinical trials are emphasized, but in many cases data from randomized controlled trials are lacking. In such cases, large case series, preliminary clinical studies, and expert opinions are utilized. Technical data are gathered from traditional and Web-based publications, proprietary publications, and informal communications with pertinent vendors.

For this review, the MEDLINE database was searched through September 2006 for articles related to endoscopy in patients with implanted electronic devices by using the keywords "gastrointestinal endoscopy" and "electrocautery" paired with "pacemaker," "defibrillator," "ICD," and each of the miscellaneous noncardiac devices. In addition, this document also received review and contributions from physician representatives of the Heart Rhythm Society (Washington, DC).

## NUMBER OF SOURCE DOCUMENTS

Not stated

# METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Not stated

#### RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

# **METHODS USED TO ANALYZE THE EVIDENCE**

Review

#### **DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE**

Not stated

## METHODS USED TO FORMULATE THE RECOMMENDATIONS

**Expert Consensus** 

# DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Technology Status Evaluation Reports are drafted by one or two members of the American Society for Gastrointestinal Endoscopy (ASGE) Technology Committee and reviewed and edited by the committee as a whole. This document also received review and contributions from physician representatives of the Heart Rhythm Society (Washington, DC).

#### RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

#### **COST ANALYSIS**

A formal cost analysis was not performed and published cost analyses were not reviewed.

#### METHOD OF GUIDELINE VALIDATION

Internal Peer Review

## **DESCRIPTION OF METHOD OF GUIDELINE VALIDATION**

This document was reviewed and approved by the Governing Board of the American Society for Gastrointestinal Endoscopy.

# **RECOMMENDATIONS**

#### **MAJOR RECOMMENDATIONS**

# **Summary Recommendations for Cardiac Devices**

By recognizing that the paucity of published clinical data favoring any given approach, that the availability of heart rhythm specialty support varies by geographic region and practice setting, and that the variation in practice currently exists in this area, the following general recommendations are made to minimize

the risks to patients with implanted cardiac devices who are undergoing endoscopic procedures that require the use of electrocautery.

- In all patients with implanted cardiac devices:
  - Determine the type of cardiac device, indication for the device, the
    patient's underlying cardiac rhythm, and degree of pacemakerdependence before endoscopy. Most patients carry wallet cards that
    identify the device make and model, with manufacturer contact
    numbers. Contacting the patient's cardiologist or heart rhythm
    specialist and/or the device manufacturer may be helpful, especially in
    concert with the evaluation by an on-site heart rhythm specialist or
    device nurse.
  - Use continuous electrocardiographic rhythm monitoring in addition to pulse oximetry during the procedure.
  - Have appropriate equipment for resuscitation, cardioversion, and defibrillation immediately available. This should include an external defibrillator with transcutaneous pacing capability.
  - Consider the use of endoscopic devices with limited or no electromagnetic field (EMF) (such as noncautery thermal probes or bipolar/multipolar probes).
  - Use the lowest effective power output and the briefest application of the electrocautery device possible.
  - Place grounding pads a good distance from the pulse generator and leads, such that the implanted device and leads are not between the cautery source and the grounding pad.
  - Avoid use of cautery near implanted devices (some investigators advise avoiding therapy within 15 centimeters).
- Most patients with cardiac pacemakers may undergo routine uses of electrocautery (e.g., polypectomy, hemostasis) with no alterations in management.
- For patients who are pacemaker dependent and in whom prolonged electrocautery is anticipated (e.g., treatment of gastric antral vascular ectasia or radiation proctitis) consider reprogramming the pacemaker to an asynchronous mode via application of a magnet over the pulse generator during the use of electrocautery.
- For patients with an implantable cardioverter-defibrillator (ICD) in whom the
  use of any electrocautery may be anticipated, consultation with a cardiologist
  or a heart-rhythm specialist is recommended. Deactivation of the ICD
  function by qualified personnel should be considered. Continuous rhythm
  monitoring should be used throughout the interval that the ICD is
  deactivated. If deactivated, the ICD should be reprogrammed as soon as
  possible after the procedure and before cessation of monitoring or dismissal.
- If the patient with an ICD is also pacemaker dependent and the ICD cannot be reprogrammed to an asynchronous mode and prolonged cautery application may be required, then strongly consider the use of bipolar cautery or a device with no EMF.

# **Summary Recommendations for Noncardiac Devices**

The type of electronic device, the indication for the device, and whether normal physiology is critically dependent upon the device should be determined. Most patients carry wallet cards that identify the device make and model, with

manufacturer contact numbers. Contacting the patient's device specialist and/or the manufacturer may be helpful in planning device management during and after the procedure.

- Consider the use of endoscopic devices with limited or no EMF (such as noncautery thermal probes or bipolar/multipolar probes).
- Use the lowest effective power output and the briefest application of the electrocautery device possible.
- Place grounding pads a good distance from the device's generator and leads, so that the implanted device and leads are not between the cautery source and the grounding pad.
- Avoid the use of cautery near implanted devices.
- For patients with deep brain stimulator (DBS) and gastric electrical stimulation (GES) devices, consult the primary device specialist before considering inactivation of the device output.
- For patients with spinal cord and most other peripheral neurologic stimulation devices, have the patient zero the voltage output and then turn off the device before use of electrocautery.

## Conclusions

Implanted electronic devices are increasingly encountered during gastrointestinal (GI) endoscopy. Endoscopists must be aware of the risks for patient injury and device damage or malfunction and must take precautionary steps to minimize the risk for their patients. The published data are quite limited. Further studies should address the risk of adverse events related to electromagnetic interference during GI endoscopy.

# **CLINICAL ALGORITHM(S)**

None provided

## **EVIDENCE SUPPORTING THE RECOMMENDATIONS**

## TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendations is not specifically stated.

# BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

## **POTENTIAL BENEFITS**

Appropriate management strategies for endoscopy and the use of electrocautery in patients with implantable electronic devices

#### **POTENTIAL HARMS**

#### **Pacemaker**

The disadvantage of magnet application is that pacemakers with magnet rates near 100 beats per minute may not be well tolerated by some patients at rest.

# Implantable Cardioverter-Defibrillator (ICD)

- There are several limitations to the approach of magnet application in patients with ICD:
  - Unlike a pacemaker response to a magnet, where asynchronous pacing can be easily observed, it is more difficult to ascertain whether the magnet is properly positioned over an ICD. The proper position varies among different device manufacturers and models, and while some devices emit a tone when a magnet is placed properly, others provide no feedback to prove proper placement.
  - Even if initially placed properly, a magnet may move out of place during the procedure, especially if patient repositioning is required.
- One limitation of ICD interrogation and reprogramming approach is the need to have qualified personnel available to perform the task immediately before and after the procedure. During this period of inactivation, patients with an ICD are not protected by the device and, hence, must be monitored continuously in a setting where ventricular tachycardia/ventricular fibrillation (VT/VF) can be immediately recognized and treated with external defibrillation. Endoscopy facilities that use an approach of ICD reprogramming should establish a fail-safe protocol for ensuring that, in patients with an ICD, the ICD is appropriately reprogrammed after the procedure and that no patient ever leaves the monitored setting with the ICD inappropriately inactivated. Several patient deaths from VT/VF have been documented because of this preventable medical error.

Refer to the original guideline document for more information.

## **QUALIFYING STATEMENTS**

# **QUALIFYING STATEMENTS**

- Technology Status Evaluation Reports are scientific reviews provided solely for educational and informational purposes. Technology Status Evaluation Reports are not rules and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment or payment for such treatment.
- Because of limited available data on the safety and effectiveness of different strategies for cardiac-device management during endoscopy, as well as different features available in different cardiac-device makes and models, universal recommendations applying to all patients in all practice settings cannot be made at the present time.

# **IMPLEMENTATION OF THE GUIDELINE**

## **DESCRIPTION OF IMPLEMENTATION STRATEGY**

An implementation strategy was not provided.

# INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

## **IOM CARE NEED**

Getting Better Living with Illness Staying Healthy

#### **IOM DOMAIN**

Safety

# **IDENTIFYING INFORMATION AND AVAILABILITY**

# **BIBLIOGRAPHIC SOURCE(S)**

Petersen BT, Hussain N, Marine JE, Trohman RG, Carpenter S, Chuttani R, Croffie J, Disario J, Chotiprasidhi P, Liu J, Somogyi L, Technology Assessment Committee. Endoscopy in patients with implanted electronic devices. Gastrointest Endosc 2007 Apr;65(4):561-8. [48 references] PubMed

#### **ADAPTATION**

Not applicable: The guideline was not adapted from another source.

#### **DATE RELEASED**

2007 Apr

# **GUIDELINE DEVELOPER(S)**

American Society for Gastrointestinal Endoscopy - Medical Specialty Society

# **SOURCE(S) OF FUNDING**

American Society for Gastrointestinal Endoscopy

#### **GUIDELINE COMMITTEE**

**Technology Assessment Committee** 

## **COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE**

Committee Members: Bret T. Petersen, MD, Chair; Nadeem Hussain, MD; Joseph E. Marine, MD\*; Richard G. Trohman, MD\*; Steven Carpenter, MD; Ram Chuttani, MD; Joseph Croffie, MD; James DiSario, MD; Poonputt Chotiprasidhi, MD; Julia Liu, MD; Lehel Somogyi, MD

\*Heart Rhythm Society representatives

# FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

#### **GUIDELINE STATUS**

This is the current release of the guideline.

## **GUIDELINE AVAILABILITY**

Electronic copies: Available from the <u>American Society for Gastrointestinal</u> Endoscopy Web site.

Print copies: Available from the American Society for Gastrointestinal Endoscopy, 1520 Kensington Road, Suite 202, Oak Brook, IL 60523

#### **AVAILABILITY OF COMPANION DOCUMENTS**

The following is available:

• Petersen BT. Implanted electronic devices at endoscopy: advice in a gray area. Editorial. Gastrointest Endosc 2007 Apr;65(4):569-70.

Electronic copies: Available from the <u>American Society for Gastrointestinal</u> Endoscopy Web site.

Print copies: Available from the American Society for Gastrointestinal Endoscopy, 1520 Kensington Road, Suite 202, Oak Brook, IL 60523

# **PATIENT RESOURCES**

None available

## **NGC STATUS**

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